



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Commercial License Agreement: Development of 5T4 antibody-drug conjugates for the treatment of human cancers

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an start-up exclusive commercial license to practice the inventions embodied in U.S. Patent Application No. 62/034,995 entitled “Human Monoclonal Antibodies Specific for 5T4 and Methods of Their Use” filed August 8, 2014 [HHS Ref. E-158-2014/0-US-01] and all related continuing and foreign patents/patent applications for the technology family to Concortis, Inc. The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective start-up exclusive commercial license territory may be worldwide and the field of use may be limited to the development of 5T4 antibody drug

conjugate therapeutics for the treatment of human cancers using Concertis' proprietary conjugation technologies.

DATED: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Whitney Hastings, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 451-7337; Facsimile: (301) 402-0220; E-mail: hastingw@mail.nih.gov.

SUPPLEMENTARY INFORMATION: 5T4 is an antigen expressed in a number of carcinomas. Its expression is limited in normal tissue, but is prevalent in malignant tumors throughout their development. This confined expression makes it an attractive target for cancer immunotherapy. 5T4 is often found in colorectal, ovarian, and gastric tumors and thus has been used as a prognostic aid for these cancers. In addition, its role in antibody-directed immunotherapy for delivering response modifiers to tumors has been studied using murine monoclonal antibodies (mAbs) and the cancer vaccine TroVax (currently in clinical trials for multiple solid tumors) targets 5T4. The present invention

describes the identification and characterization of two fully human mAbs (m1001 and m1002) that bind to 5T4. Since the mAbs are fully human, they could have less immunogenicity and better safety profiles than the existing mouse and humanized antibodies.

The prospective start-up exclusive commercial license is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective start-up exclusive commercial license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Any additional, properly filed, and complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive commercial license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: March 17, 2015.

Richard U. Rodriguez,
Acting Director,
Office of Technology Transfer,
National Institutes of Health.

[FR Doc. 2015-06488 Filed: 3/20/2015 08:45 am; Publication Date: 3/23/2015]